

50. (Amended) A pharmaceutical composition for administration of a hydrophobic drug comprising:

- (a) a therapeutically effective amount of a hydrophobic drug; and
- (b) a vitamin E substance,

wherein the hydrophobic drug is present in an amount of from about 0.1 to 30 % w/w of the composition and is at least about 50 % solubilized in the composition, and wherein the vitamin E substance is present in an amount of from about 20 wt. % to about 95 wt. % of said composition.

REMARKS

THE ABOVE AMENDMENTS:

Non-elected claims 13-36 have been canceled without prejudice. Applicants expressly reserve the right to file one or more divisional applications hereof in order to prosecute the subject matter of the now-canceled claims.

In addition, claim 50 has been amended to more clearly define the invention. The claim now recites that the vitamin E substance is present an amount in the range of about 20 wt.% to 95 wt.% of the composition. Support for the lower limit of about 20 wt. % can be found in the specification at, for example, page 21, line 4. Support for the upper limit of about 95 wt.% can be found in the specification at, for example, page 21, line 3. No new matter has been entered.

A redacted version of the amended claim indicating the amendments thereto is attached as Appendix A.

RESPONSE TO REQUIREMENT FOR RESTRICTION:

The Examiner has required restriction between three groups of claims:

Group (I), claims 1-12 and 50, drawn to a composition comprising a hydrophobic active agent such as fenofibrate, a vitamin E substance, a trialkyl citrate, a lactone, a nitrogen-containing solvent or combinations thereof;

Group (II), claims 13 and 14, drawn to a composition comprising fenofibrate and a phospholipid; and

Group (III), claims 15-36, drawn to a composition comprising fenofibrate and a solubilizer consisting essentially of a glycerol fatty acid ester, a propylene glycol ester, an

ethylene glycol ester, a propylene glycol ester, a lower alcohol fatty acid ester or a mixture thereof.

The Examiner notes that claims 37-49 and 51 would be examined along with the elected group.

In response, applicants elect the claims of Group (I), without traverse. Accordingly, claims 1-12, 37-49, 50 and 51 are now pending.

The Examiner is welcome to contact the undersigned at 650-851-8501 with any questions he may have concerning this communication or the subject application.

Respectfully submitted,

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APPENDIX A

REDACTED VERSION OF THE CLAIMS SHOWING THE AMENDMENTS MADE:

Cancel claims 13-36 without prejudice.

Amend claim 50 as follows:

50. (Amended) A pharmaceutical composition for administration of a hydrophobic drug comprising:

- (a) a therapeutically effective amount of a hydrophobic drug; and
- (b) a vitamin E substance,

wherein the hydrophobic drug is present in an amount of from about 0.1 to 30 % w/w of the composition and is at least about 50 % solubilized in the composition, and wherein the vitamin E substance is present in an amount of from about ~~1 to 99 % w/w~~ 20 wt. % to about 95 wt. % of said composition.